JUL 11 2001

K002207

ADMINISTRATIVE INFORMATION

Manufacturer Name: MacroPore, Inc.
6740 Top Gun Street
San Diego, CA 92121

Official Contact: Kenneth K. Kleinhenz
Director of Regulatory Affairs
Telephone (858) 458-0900
Fax (858) 458-0994

DEVICE NAME

Classification Name: Plate, Bone

Trade/Proprietary Name: MacroPore*PX* Pediatric System

ESTABLISHMENT REGISTRATION NUMBER

2031733

DEVICE CLASSIFICATION AND PRODUCT CODE

As shown in 21CFR 888.3030 - Bone Fixation Appliances (Bone Plates) and 21 CFR 888.3040 - Bone Fixation Fasteners are intended for use in trauma and reconstructive procedures for bone fixation and are classified as Class II. Bone Plates have been assigned Product Code HRS, Bone Fixation Fasteners are assigned Prodcut Code HWC.

INTENDED USE

MacroPore*PX* Pediatric System is intended for use in trauma and reconstructive procedures in the midface and craniofacial skeleton:

1). Comminuted fractures of the naso-ethmoidal and infraorbital areas
2). Comminuted fractures of the frontal sinus wall
3). Trauma of the midface or craniofacial skeleton
4). Reconstructive procedures of the midface or craniofacial skeleton

The system is not intended for use in the mandible and/or full load bearing procedures.

DEVICE DESCRIPTION

Design Characteristics

The MacroPore*PX* System is fabricated from a copolymer of polylactic acid and polyglycolic acid. The MacroPore*PX* System is composed of resorbable plates, protective sheets, screws and tacks. Components of the MacroPore*PX* System are provided in various shapes and sizes and will be provided in larger sizes as needed for particular surgical procedures. The dimensional and size restrictions will be consistent with those cleared in the predicate device (Protego System K972913). Various manual instruments (drills, taps, PowerPen, PowerBath, screw drivers, tack drivers, etc.) are used in conjunction with the MacroPore*PX* System to assist in the installation process.

The MacroPore*PX* Plates and Protective Sheets can be cut with scissors to the desired shape and size. The MacroPore Power Pen can also be used to cut or shape the Plates or Protective Sheet to the desired shape or size. The Plates and Protective Sheets are fully malleable when heated to approximately 55°C (for example, by the use of sterile hot water), and thus can be conformed three dimensionally to most any anatomical orientation. The Protective Sheet can be rolled into a tube or used as a flat sheet. It can be used either alone or in conjunction with internal bone fixation devices such as plates and screws, which also can serve to fixate the MacroPore*PX* Protective Sheet and prevent dislocation.

Material Composition

The MacroPore*PX* System is fabricated from a copolymer of polylactic acid and polyglycolic acid.

In Vitro Testing

Mechanical testing of the MacroPore*PX* System demonstrates that the device is substantially equivalent to the predicate. Test results indicate that the mechanical properties of the MacroPore*PX* System are substantially equivalent to the mechanical properties of the predicate MacroPore Protego System (plates, mesh, tacks, and screws) under indication for use conditions.

EQUIVALENCE TO MARKETED PRODUCT

MacroPorePX System shares indications and design principles with the MacroPore Protego System device, which has been determined by FDA to be substantially equivalent to a pre-amendment devices under (K972913). The differences between the MacroPore Protego System plates and screws and the MacroPorePX System are limited to the following:

- Dimensional changes – within maximum size limitations of Protego K972913
- Dimensional changes – within minimum strength limitations of Protego K972913
- Material change - represented by legally marketed devices with like CFR classifications and indications

Through design control assessment, including verification and validation, MacroPore has demonstrated that the modifications to the MacroPore Protego System (plates, mesh, tacks, and screws) do not alter the device's intended use or indications, nor have the principles of operation or the technical characteristics been altered. Therefore, the MacroPore*PX* System is substantially equivalent to the MacroPore Protego System.

Indications For Use

The proposed indications for use of MacroPore*PX* System is identical to the MacroPore Protego System's (K972913) indications for use as both products are intended for use in trauma and reconstructive procedures in the midface and craniofacial skeleton:

1). Comminuted fractures of the naso-ethmoidal and infraorbital areas
2). Comminuted fractures of the frontal sinus wall
3). Trauma of the midface or craniofacial skeleton
4). Reconstructive procedures of the midface or craniofacial skeleton

The system is not intended for use in the mandible and/or full load bearing procedures.

Design and Materials

Both the MacroPore*PX* System and the predicate device are manufactured from bioabsorbable materials under substantially equivalent conditions. The physical designs of MacroPore*PX* System and the predicate device are substantially equivalent, consisting of a plates, screws, tacks, and protective sheets. The MacroPore*PX* and the predicate are substantially equivalent with respect to science and technology as they share modes of bone fixation, fundamental manufacturing technology, biocompatability, and operating principles. The mechanical characteristics of the MacroPore*PX* System and the predicate device are substantially equivalent to the predicate device under indications for use conditions. The material used in the MacroPore*PX* System is represented by several legally marketed devices fabricated from a polylactic acid, polyglycolic acid copolymer, all sharing the same indications for use as well as the same CFR classifications. In addition to physical characteristics, both the predicate device and the MacroPore*PX* Pediatric System can be cut and molded to specific shapes and sizes by the end user.

The modifications made to the MacroPore Protego System device does not alter the fundamental scientific technology or the principles of operation of the device. The material change and the minor changes to shapes and sizes do not alter the device's operating principle as both the predicate device and the MacroPore*PX* device utilize plates and protective sheets that are fixated to bone with screws or tacks. The MacroPore*PX* System and the MacroPore Protego System devices share the same principles of operation by stabilizing craniofacial bone *in vivo* through the use of plates and protective sheets that are secured to bone with tacks or screws. Additionally, there are no changes to the scientific technology as the MacroPore*PX* System and the predicate MacroPore Protego System device (K972913) utilizes the same manufacturing technology and share material characteristic of bioabsorbability.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 11 2001

Mr. Kenneth K. Kleinhenz
Director of Regulatory Affairs
Macropore, Incorporated
6740 Top Gun Street
San Diego, California 92121

Re: K002207
Trade/Device Name: MacroPore PX Pediatric System
Regulation Number: 872.4760
Regulatory Class: II
Product Code: JEY
Dated: April 12, 2001
Received: April 13, 2001

Dear Kleinhenz:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note:

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K002207

Device Name: MacroPore *PX* Pediatric System

Indications for Use:

A. General Indications: Trauma procedures of the midface or craniofacial skeleton.
Specific Indications:
1). Comminuted fractures of the naso-ethmoidal infraorbital areas.
2). Comminuted fractures of the frontal sinus wall.
3). Pediatric midface or craniofacial trauma
4). Lefort (I, II, III) fractures.
5). Orbital floor fractures.
6).Fractures of the maxilla, zygoma, zygomatic arch, orbital rim, nasal, ethmoid, and lacrimal bones.
7). Trauma of the craniofacial skeleton including: frontal, parietal, temporal , sphenoid, and occipital bones.

B. General Indications: Reconstructive procedures of the midface or craniofacial skeleton..
Specific Indications:
1). Infant craniofacial surgery (i.e., craniosynostosis, congentital malformations, traum etc.).
2). Lefort (I, II, III) osteotomies.
3). Tumor reconstruction in midface or craniofacial procedures.
4). Bone graft procedures in the midface or craniofacial skeleton.
5). Pediatric reconstructive procedures.
6). Reconstructive procedures of the craniofacial skeleton including: frontal, parietal, temporal, sphenoid, and occipital bones.
7). Craniotomy flap fixation.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ Susan Runner OR Over-The-Counter Use _____

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K002207